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Proposed Registration Decision PRD2012-33

Whole Egg Solids, Wintergreen Oil, Castrol Oil Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids

(publié aussi en français)

14 December 2012

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2012-33E (print version)
H113-9/2012-33E-PDF (PDF version)

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Table of Contents

Overview 1
Proposed Registration Decision for Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids 1
What Does Health Canada Consider When Making a Registration Decision? 2
What Are Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture Capsaicin and Related Capsaicinoids? 2
Health Considerations 3
Environmental Considerations 4
Value Considerations 4
Measures to Minimize Risk 5
Next Steps 6
Other Information 6
Science Evaluation 7
1.0 The Active Ingredient, Its Properties and Uses 7
2.0 Methods of Analysis 7
3.0 Impact on Human and Animal Health 7
4.0 Impact on the Environment 7
5.0 Value 7
5.1 Effectiveness Against Pests 7
6.0 Pest Control Product Policy Considerations 8
7.0 Summary 8
7.1 Human Health and Safety 8
7.2 Environmental Risk 9
7.3 Value 9
8.0 Proposed Regulatory Decision 9
References 11

Overview

Proposed Registration Decision for Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray containing the active ingredients Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids to prevent feeding damage to outdoor ornamental plants by white-tailed deer and black-tailed deer.

Dried Whole Eggs (Registration Number 29803), Bobbex Deer Repellent RTU Technical (Registration Number 29829), Bobbex Deer Repellent Concentrate Technical (Registration Number 29830), Bobbex Deer Repellent Concentrate (Registration Number 29804) and Bobbex Deer Repellent Ready-To-Use Spray (Registration Number 29805) are conditionally registered in Canada. The detailed review for Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray can be found in Evaluation Report ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids*. The current applications were submitted to convert Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Are Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture Capsaicin and Related Capsaicinoids?

Whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids prevents feeding damage by white-tailed and black-tailed deer to outdoor ornamentals by combining both odour and taste repellents.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Health Considerations

Can Approved Uses of Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and related Capsaicinoids Affect Human Health?

Whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are unlikely to affect your health when used according to label directions.

Exposure to whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids may occur when handling and applying the products, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray, as well as during typical residential activities following application. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Eggs, fish, and garlic are known to cause allergic reactions in sensitive individuals. Precautionary statements alerting users of the potential for an allergic reaction in individuals sensitive to eggs, fish, and garlic are required on the product labels for both Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray.

Inhalation, dermal, and ocular exposures are possible when applying the product, particularly to the applicator and bystanders located near the treatment area. Also, entry into a recently sprayed area may result in dermal exposure. Therefore, spray advisory and restricted entry statements are required on the end-use product labels to minimize applicator and bystander exposures.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use pattern of Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray do not include food or feed crops. The active ingredients are found in foods and consumer products and any residues that may occur in drinking water from the use pattern are not expected to pose a concern to human health.

Occupational Risks from Handling Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray

Occupational risks are not of concern when Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray are used according to label directions, which include protective measures.

Domestic users handling and applying Bobbex Deer Repellent Concentrate or Bobbex Deer Repellent Ready-To-Use Spray to areas that attract deer, such as trees, plants, shrubs, flowers, and non-flowering plants, can come in direct contact with the active ingredients on the skin and in the eyes. Following the precautionary label statements aimed at minimizing exposure to the product will ensure domestic users are appropriately protected. The potential for inhalation while handling and applying the product will be negligible when users observe the precautionary label statements.

Accidental bystander exposure is possible from spray drift, but exposure is expected to be negligible when the precautionary label statements are observed by the applicator.

Post-application exposure is possible in individuals who immediately enter freshly treated areas. People who are allergic to eggs, fish or garlic should exercise precaution before entering freshly treated areas.

Environmental Considerations

What Happens When Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids are Introduced Into the Environment?

Whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are expected to degrade rapidly in the environment. The active ingredients are food grade, and have a non-toxic mode of action, i.e.; they act as a repellent. Environmental exposure is expected to be minimal when the end-use products containing these active ingredients are used under the current domestic use pattern.

Value Considerations

What Is the Value of Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray?

Bobbex Deer Repellent Concentrate applied at a dilution of 1 part product to 5 parts water and Bobbex Deer Repellent Ready-To-Use Spray prevents feeding damage to outdoor ornamentals by white-tailed and black-tailed deer by combining both odour and taste repellents. Both of these products are compatible with an Integrated Pest Management (IPM) program to prevent deer damage to ornamental plants.

Confirmatory efficacy data were required testing Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray on herbaceous ornamental plants species to prevent feeding damage to outdoor ornamentals by white-tailed and black-tailed deer.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray to address the potential risks are as follows.

Key Risk-Reduction Measures

Human Health

The statement, "Warning, contains the allergen egg", has been included on the principal display panel of the technical product label for Dried Whole Eggs and "Warning, contains the allergen fish" on the principal display panel of the technical product labels for each of the technical products. The statements, "DANGER – EYE IRRITANT", "CAUTION – SKIN IRRITANT", "POTENTIAL SENSITIZER", and "Warning, contains the allergens egg and fish" have been included on the principal display panel of the end-use product labels and "Severely irritating to the eye", "DO NOT get in eyes", "May irritate skin", "Avoid inhaling as a mist or dust on drying, and "May cause sensitization. DO NOT apply if allergic to eggs or fish. DO NOT apply if sensitive or allergic to garlic." have been included in the PRECAUTIONS section of the secondary display panel of both end-use product labels.

Because some individuals may be sensitive to eggs, fish, or garlic, for example, allergic, the statements, "Apply only when the potential for drift is minimal", "Individuals who are sensitive or allergic to eggs, fish, or garlic should avoid handling Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray" and "Individuals who are sensitive or allergic to eggs, fish, or garlic should avoid treated areas have dried or until after a heavy rain" have also been included in the PRECAUTIONS section of the secondary display panel of the product labels.

Next Steps

Before making a final registration decision on Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids (based on the Science Evaluation of this consultation document and Evaluation Report ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids*). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

1.0 The Active Ingredient, Its Properties and Uses

Please refer to Evaluation Report ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids* for a detailed assessment of the active ingredient, its properties and uses.

2.0 Methods of Analysis

Please refer to Evaluation Report ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids* for a detailed assessment of the methods of analysis.

3.0 Impact on Human and Animal Health

Please refer to Evaluation Report ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids* for a detailed assessment of the impact on human and animal health.

4.0 Impact on the Environment

Please refer to Evaluation Report ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids* for a detailed assessment of the impact on the environment.

5.0 Value

Please refer to Evaluation Report ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids* for a detailed assessment of the value of the end use products.

5.1 Effectiveness Against Pests

As indicated in Evaluation Report ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids*, confirmatory efficacy data were required testing Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray on herbaceous ornamental plants species to prevent feeding damage to outdoor ornamentals by white-tailed and black-tailed deer.

Two efficacy trials (1 on hostas in 2008 and 1 on yews from 2006-2007) conducted in Connecticut using white-tailed deer were submitted. The trial on hosta demonstrated that the Bobbex products reduced white-tailed deer damage when applied according to the directions for use once every two weeks. The trial on yews demonstrated that the Bobbex products reduced white-tailed deer damage when applied according to the directions for use once every 17 to 19 days.

6.0 Pest Control Product Policy Considerations

Please refer to Evaluation Report ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids* for information on pest control product policy considerations.

7.0 Summary

7.1 Human Health and Safety

The available toxicological information on whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids is adequate to identify the majority of toxic effects that may result from exposure to the active ingredients. Eye and skin irritation is possible, as well as allergic reactions in individuals sensitive to eggs, fish, or garlic. No other toxicologically significant effects were reported in available information on whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids.

The precautionary statements on the product labels are adequate to protect applicators and bystanders. The product label instructs domestic users to not apply Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray if there is the potential for spray drift from targeted areas. Judicious application of the product is not expected to result in applicators being exposed to concentrations of egg, fish, or garlic that would be of concern. Furthermore, allowing Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray to dry after each application will ensure that bystanders and pets are unlikely to come in contact with eggs, fish, or garlic at concentrations that would be of concern.

Because Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray are not to be applied to food or feed crops, the establishment of a maximum residue limit was not required for whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids

Individuals who are allergic to eggs, fish, or garlic are advised to avoid handling Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray, as well avoid entering treated areas until sprayed residues have dried completely.

7.2 Environmental Risk

Based on limited exposure, the chemical's natural occurrence and the likelihood for relatively rapid transformation under environmental conditions, the use of whole egg solids, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are not expected to pose a significant risk to the environment.

7.3 Value

Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray repel white-tailed and black-tailed deer on conifers for up to 28 days and up to 14 days for other outdoor ornamental plants.

8.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Dried Whole Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray containing the active ingredients Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids to prevent feeding damage to outdoor ornamental plants by white-tailed deer and black-tailed deer.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and does not present an unacceptable risk to human health or the environment.

References

A. List of Studies/Information Submitted by Registrant

1.0 Value

2120972 2010, Effectiveness of Deer Repellents in Connecticut, DACO: 10.2.3.3

2120973 2011, Deer Repellent Trial Summary Report 2011, DACO: 10.2.3.3

2120986 2010, Effectiveness of Deer Repellents in Connecticut, DACO: 10.2.3.3

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